CYTODYN INC
Form 10-K
August 22, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended May 31, 2012

or

¨ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Colorado	**75-3056237**
(State or other jurisdiction of	**(I.R.S. Employer**

incorporation or organization)	Identification No.)
110 Crenshaw Lake Road, Lutz, Florida	**33548**
(Address of principal executive offices)	**(Zip Code)**

Registrant s Telephone Number, including area code: (813) 527-6969

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Title of class

Common Stock, no par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ¨ Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act). ¨ Yes x No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter: $29,890,680 (as of November 30, 2011).

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. As of July 31, 2012, the registrant had 29,211,509 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Parts Into Which Incorporated

Portions of Proxy Statement for the 2012 Annual Meeting of Shareholders (Proxy Statement) Part III

Table of Contents

CYTODYN INC

FORM 10-K FOR THE YEAR ENDED MAY 31, 2012

Table of Contents

Table of Contents

THROUGHOUT THIS FILING, WE MAKE FORWARD-LOOKING STATEMENTS. THE WORDS ANTICIPATE, BELIEVE, EXPECT, INTEND, PREDICT, PLAN, SEEK, ESTIMATE, PROJECT, WILL, CONTINUE, COULD, MAY, AND SIMILAR TERM EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS. THESE STATEMENTS INCLUDE, AMONG OTHERS, INFORMATION REGARDING FUTURE OPERATIONS, FUTURE CAPITAL EXPENDITURES, AND FUTURE NET CASH FLOWS. SUCH STATEMENTS REFLECT THE COMPANY S CURRENT VIEWS WITH RESPECT TO FUTURE EVENTS AND FINANCIAL PERFORMANCE AND INVOLVE RISKS AND UNCERTAINTIES, INCLUDING, WITHOUT LIMITATION, GENERAL ECONOMIC AND BUSINESS CONDITIONS, CHANGES IN FOREIGN, POLITICAL, SOCIAL, AND ECONOMIC CONDITIONS, REGULATORY INITIATIVES AND COMPLIANCE WITH GOVERNMENTAL REGULATIONS, THE ABILITY TO ACHIEVE MARKET PENETRATION AND ATTRACT CUSTOMERS, AND VARIOUS OTHER MATTERS, MANY OF WHICH ARE BEYOND THE COMPANY S CONTROL. SHOULD ONE OR MORE OF THESE RISKS OR UNCERTAINTIES OCCUR, OR SHOULD UNDERLYING ASSUMPTIONS PROVE TO BE INCORRECT, ACTUAL RESULTS MAY VARY MATERIALLY AND ADVERSELY FROM THOSE ANTICIPATED, BELIEVED, ESTIMATED, OR OTHERWISE INDICATED. CONSEQUENTLY, ALL OF THE FORWARD-LOOKING STATEMENTS MADE IN THIS FILING ARE QUALIFIED BY THESE CAUTIONARY STATEMENTS AND THERE CAN BE NO ASSURANCE OF THE ACTUAL RESULTS OR DEVELOPMENTS.

PART I

Item 1. Business.

Overview / Corporate History

CytoDyn Inc. (the Company), is a Colorado corporation, with its principal business office at 110 Crenshaw Lake Road, Lutz, Florida 33548; telephone: (813) 527-6969, facsimile: (813) 527-6970, and website address: www.cytodyn.com. We are a development stage biotechnology company (concept company) focused on discovering and developing a class of therapeutic monoclonal antibodies to treat Human Immunodeficiency Virus (HIV) infection. In addition, we formed a wholly owned subsidiary, CytoDyn Veterinary Medicine LLC (CVM), which will explore the possible application of our existing proprietary monoclonal antibody technology to the treatment of Feline Immunodeficiency Virus, a retroviral infection in cats (FIV).

In October 2003, the Company (under its previous name RexRay Corporation) entered into an Acquisition Agreement with CytoDyn of New Mexico, Inc. Pursuant to the acquisition agreement, we acquired assets related to our leading drug candidate, Cytolin®, including the assignment of the patent license agreement dated July 1, 1994 between CytoDyn of New Mexico, Inc. and Allen D. Allen covering three United States patents along with foreign counterpart patents which describe a method for treating HIV disease with the use of monoclonal antibodies. This includes issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057, as well as European Patent Nos. 0690725 and 1438970. In addition, Hong Kong Patent No. 1067958,

Table of Contents

Australian Patent Nos. 684074 and 2003203742, Canadian Patent No. 2156495, Austrian Patent Nos. 408418, 267019, and 1438970, Belgian Patent No. 1438970, Swiss Patent Nos. 1438970 and 0690725, German Patent Nos. 69433789 and 69435142.3, Danish Patent No. 1438970, Spanish Patent Nos. 2219647, 2314341, 04101437.4, and 94912826.8, French Patent Nos. 1438970 and 0690725, Great Britain Patent Nos. 1438970 and 069725, Greece Patent No. 3067384, Iceland Patent No. 1438970, Italian Patent Nos. 1438970 and 0690725, Luxenbourg Patent No. 1438970, Monaco Patent No. 1438970, Netherlands Patent Nos. 1438970 and 0690725, Portuguese Patent Nos. 690725 and 1438970, and Swedish Patent Nos. 0410437.4 and 94912826.8 have been obtained as well. We also acquired the federally registered trademarks, CYTODYN (U.S. Registration No. 2095498) and CYTOLIN (U.S. Registration No. 2095497), and a related design mark (U.S. Registration No. 2662777. The license acquired gives the Company the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent claims, practice methods taught by the patent claims, and exploit specified technology related to the patents. The term of the license agreement is for the life of the patents of which the first will expire in 2013. The original expiration dates on the issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057 are 2013, 2014 and 2013, respectively. The original expiration dates for the foreign patents listed above are in 2013 or 2014, if the required annuity fee payments are paid by September 21, 2012. The Company s Cytolin-related patents referenced above are for a murine (mouse) version of the drug. The Company s research on Cytolin® to date has utilized the current murine version of the drug. However, on September 23, 2011, the Company filed a provisional patent application (Serial No. 61/534,942) in the United States for its humanized version of Cytolin®, a monoclonal antibody for the treatment of HIV Infection.

The Company is also exploring other antibodies as potential therapeutics for FIV. On June 17, 2011, the Company filed a provisional patent application in the United States (Serial No. 61/498,029) for the use of these antibodies as well as selected small molecule antagonists and agonists for the treatment of FIV. On June 15, 2012, the Company filed an international patent application (Serial No. PCT/US2012/042693) claiming priority to this provisional patent application. On August 10, 2011, the Company filed an application for registration of the trademark CYTOFELINE, intended for use in conjunction with veterinary preparations for the treatment of FIV (U.S. App. Ser. No. 85393956). In February 2012, the Company filed foreign trademark applications claiming priority to the US application for CYTOFELINE, including Australian App. No. 1473043, Canadian App. No. 1563313, European CTM App. No. 010625192, Indian App. No. 2279431, Japan App. No. 2012-008009, Mexican App. No. 1247597, and a Chinese App. No. 10475960. Thus far, the Company has received a Certificate of Trademark Registration from Japan No. 5488875, with an effective registration date of April 20, 2012, and a Certificate of Trademark Registration from the European Union No. 010625192 with an effective registration date of June 11, 2012. Additionally, the Company s Australian App. No. 1473043 was registered on May 31, 2012.

Research History of Cytolin Compound

Cytolin® is part of a class of drugs called monoclonal antibodies. It targets a normal cell molecule called CD11a, part of the heterodimer that makes up the cell adhesion molecule lymphocyte function cell associated antigen (LFA-1). Published reports have suggested that blocking or engaging CD11a might somehow limit or prevent HIV infection of CD4 cells and monocytes. In 1993, six HIV-infected patients were treated with murine Cytolin®. Blood and skin tests of these patients suggested that the antibody might be producing improvements in the

Table of Contents

immune function of each patient. Based on the results of this pilot study, a compassionate use trial was initiated. In this study a relatively small number of physicians in the United States administered Cytolin® to their HIV-infected patients over two years. As results from this initial use became available, other physicians obtained and administered Cytolin® to their patients as well. Four of the doctors using Cytolin® allowed the Company s predecessor to send in an independent Institutional Review Board to inspect the medical records of approximately 200 patients treated with Cytolin® once or twice a month over 18 months. Data were recorded and summarized and formed part of the material presented to the U.S. Food & Drug Administration (the FDA) as an early indication of the safety and potential efficacy of Cytolin®.

In 1996, the FDA approved a drug master file, designated BB-DMF#6836, for the manufacture of murine Cytolin® at Vista Biologicals Corporation. CytoDyn of New Mexico, Inc. (a predecessor to the Company) and Vista Biologicals Corporation worked cooperatively to develop the drug master file. In accordance with the practice of the FDA, the drug master file was issued to and became the property of the entity with the capacity to manufacture the drug, in this case Vista Biologicals Corporation. By contract with Vista Biologicals Corporation, CytoDyn of New Mexico, Inc. had the exclusive right to reference the drug master file, that is, to authorize Vista Biologicals Corporation to manufacture Cytolin® in accordance with the terms of the drug master file.

In 1996, the FDA also designated our investigational new drug application for murine Cytolin® as BB-IND #6845, and subsequently approved a clinical trial. In 2002, Symbion Research International, a contract research organization, completed a Phase I a/b clinical trial of Cytolin® (a Phase I trial includes the initial introduction of an investigational new drug or biologic into humans). The trial was sponsored by Amerimmune, Inc., the previous licensee of CytoDyn of New Mexico, Inc. but Symbion was never paid for its work. As a result, its work product became Symbion s. We entered into a buy-sell agreement with Symbion to purchase the Phase Ia study data in 2004. The Phase Ia study, conducted in 13 subjects suffering from HIV/Acquired Immune Deficiency Syndrome (AIDS), found Cytolin® to be safe and well tolerated. The initial safety study supported the safety and tolerability of the drug in these dose groups. Some of the data was presented as an abstract and poster session, entitled Phase I Study of Anti-LFA-1 Monoclonal Antibody (Cytolin® in Adults with HIV Infection) at the 9th Conference on Retroviruses and Opportunistic Infections held in Seattle, Washington on February 24-28 2002 as well as the 16th International AIDS Conference held August 2006 in Toronto, Canada. The Company then went through a period of years where legal issues delayed the progress of this treatment.

To date, only the murine version of Cytolin® has been tested in clinical, research and development studies. The Company understands that registrational studies will require similar testing and confirmation of activity with its proprietary humanized version of Cytolin®.

Cytolin - Current Research

Under a Clinical Trial Agreement dated September 28, 2009 and as amended to date (the Clinical Trial Agreement), in exchange for a research grant by the Company, Massachusetts General Hospital (MGH) in Boston, Massachusetts agreed to conduct an ex-vivo study of murine Cytolin® in accordance with a study protocol entitled An observational study to determine the in-vitro immunologic and virology activity of Cytolin® (the Study). In addition to providing financial support for the Study, the Company agreed to provide MGH with supplies of Cytolin® needed for the Study. Under the Clinical Trial Agreement, Eric S. Rosenberg, M.D. is designated as the Principal Investigator for the Study.

Table of Contents

Human subjects were recruited for the Study from Dr. Rosenberg s clinic. The Study enrolled 10 adults with early HIV infection and 10 healthy adults as the control arm, all of whom were required to participate for six months. None of the patients enrolled in the study received injections of murine Cytolin®; rather they donated blood to allow one to examine the effects of Cytolin® when it was added in the test tube to their peripheral blood mononuclear cells. The Study design and objectives are available to view at the government s website at www.clinicaltrials.gov, ID NCT01048372. The public has online access to this federal database, which describes elements of clinical trials and their status. To review public records for the Study on the government s website, enter Cytolin as the search term (case sensitive).

The second amendment to the Clinical Trial Agreement provided that our research grant commitment for the Study would total $316,755. In March 2010, we agreed in a third amendment to the Clinical Trial Agreement to provide an additional $233,815 for the Study to enable the Principal Investigator to engage additional personnel. In December 2010, we further agreed in a fourth amendment to the Clinical Trial Agreement to provide an additional $25,000 for the Study. On May 20, 2011, we entered into a fifth amendment of the Clinical Trial Agreement with The General Hospital Corporation, d/b/a/ MGH to extend the Study enabling MGH Principal Investigator Eric Rosenberg, M.D., to further explore his initial findings regarding the potential mechanism of action of murine Cytolin® to treat HIV-positive adults. Under the fifth amendment, we agreed to pay MGH the remaining unpaid balance of $291,590 of the total research grant of $865,375 over the six month period beginning on May 20, 2011 and ending on November 20, 2011. As of May 31, 2012, the final payment in the amount of approximately $72,898 due to MGH in connection with the Clinical Trial Agreement was past due. The Study was completed subsequent to May 31, 2012. The Company anticipates that if there is sufficient data to warrant publication Dr. Rosenberg will draft and submit a manuscript detailing his results. The release of this or any data from the Study is entirely dependent on Dr. Rosenberg.

The Study was a science-intensive research study and was not intended to function as a registrational study (see Registrational Clinical Trials Process below). The Company contemplates that the Study may be followed by a clinical trial that may or may not be conducted at MGH or with Dr. Rosenberg as the Principal Investigator. The Company will determine if clinical trials with the humanized version of Cytolin® are warranted based on these and other results from studies with the murine molecule and subsequent confirmation of activity with the humanized version of Cytolin®. There is no assurance that the results of the Study will warrant further clinical trials, or that a strategic alliance for humanized Cytolin® will be available.

The Clinical Trial Agreement governs the parties rights in Study data and the results of the Study (Study Data and Results). MGH retains ownership of all Study Data and Results, and is obligated to provide the Company with a copy of such Study Data and Results. The Clinical Trial Agreement places limits on the Company s ability to use Study Data and Results. Specifically, the Company is permitted to use Study Data and Results that disclose individually identifiable health information only for purposes of the Study or related studies that concern murine Cytolin® or medical conditions / disease area that are the subject of the Study, however, the Company is permitted to use information that is not identifiable for any research and development purposes. These uses are further limited by the requirements that any such use comply with applicable law (including the Health Insurance Portability and Accountability Act of 1996 (HIPAA)); and that the use is permitted by the informed consent form used with subjects in connection with the Study.

Table of Contents

Why Cytolin May Be a Unique Treatment for Early HIV Infection

The particular epitope recognized by murine Cytolin® is highly expressed on killer cells called cytotoxic T cells or CTLs. However, subsequent studies and analysis of the activity of Cytolin® has shown that while Cytolin® is highly expressed on CTLs, this antibody does not block CTLs. In addition to being expressed on CTLs, the CD11a protein has also been reported to be present on the surface of the HIV virion, presumably to assist in the infectious cycle of the virus. This opens the possibility that Cytolin® may bind and neutralize HIV, providing a direct action against the virus in the bloodstream.

In addition to CTLs, murine Cytolin® also recognizes and binds to dendritic cells (DCs). These two types of immune cells are critical to the control of viral burden in HIV infected individuals. By binding to these cells, it is also possible that Cytolin® may induce an antiviral activity that may impede infection of new cells and presumably lead to a reduction in viral burden.

Acquisition of Advanced Genetic Technologies, Inc.

On January 30, 2007, we acquired, from Utek Corp., our subsidiary Advanced Genetic Technologies, Inc., which holds the exclusive right to develop alternative antibodies that bind to the same cellular target as murine Cytolin®. These two monoclonal antibodies were invented at Harvard University Medical School s CBR Institute for Biomedical Research. The Company has not used these two antibodies in our research and development efforts to date but we may use these in future research and development efforts.

Formation of CytoDyn Veterinary Medicine LLC and Current Research

On May 16, 2011, we formed a wholly owned subsidiary, CVM, which will explore the possible application of feline reactive monoclonal antibodies for the treatment of the feline immunodeficiency virus (FIV). We view the formation of CVM and the exploration of CD11a-specific monoclonal antibodies to treat FIV as an effort to strategically diversify the use of monoclonal antibody expertise.

On June 17, 2011, the Company filed a provisional patent application in the United States (Serial No. 61/498,029) for the use of certain antibodies as well as selected small molecule antagonists and agonists for the treatment of FIV. On June 15, 2012, the Company filed an international patent application (Serial No. PCT/US2012/042693) claiming priority to this provisional patent application. On August 10, 2011, the Company filed an application for registration of the trademark CYTOFELINE, intended for use in conjunction with veterinary preparations for the treatment of FIV (U.S. App. Ser. No. 85393956). In February 2012, the Company filed foreign trademark applications claiming priority to the US application for CYTOFELINE, including Australian App. No. 1473043, Canadian App. No. 1563313, European CTM App. No. 010625192, Indian App. No. 2279431, Japan App. No. 2012-008009, Mexican App. No. 1247597, and a Chinese App. No. 10475960. Thus far, the Company has received a

Table of Contents

Certificate of Trademark Registration from Japan No. 5488875, with an effective registration date of April 20, 2012, and a Certificate of Trademark Registration from the European Union No. 010625192 with an effective registration date of June 11, 2012. Additionally, the Company s Australian App. No. 1473043 was registered on May 31, 2012.

On November 16, 2011, the Company and The Scripps Research Institute, a nonprofit institution (Scripps Research) entered into a six-month Research Funding and Option Agreement (the Scripps Agreement) that enabled Dr. John H. Elder, Professor in the Department of Immunology and Microbial Science at Scripps Research, to explore the potential application of the Company s recently provisionally patented technology as an effective therapy in the treatment of FIV. The Company has assigned the Scripps Agreement to CVM. This study has now been completed. Through the course of this work Dr. Elder was able to identify a panel of anti-human monoclonal antibodies to CD11a that cross react with feline CD11a. These antibodies limited FIV infection in cell culture. The Company anticipates that if the data warrants publication Dr. Elder will draft and submit a manuscript detailing his results. The release of this or any data from this study is entirely dependent on Dr. Elder. While the original six-month period contemplated under the Scripps Agreement has expired, the Company will continue to engage Dr. Elder and Thomas Fitting, Esq., Ph.D., Chief Patent Counsel at Scripps Research, as consultants on an as needed basis through July 12, 2013.

On February 15, 2012, the Company and Colorado State University (CSU) entered into a Research Funding and Option Agreement (the CSU Agreement) that will enable Dr. Susan VandeWoude Associate Dean for Research and Graduate Education, CVMBS; Professor, DMIP, to explore the potential application of the Company s recently provisionally patented technology as an effective therapy in the treatment of FIV in infected cats. The Company has assigned the CSU Agreement to CVM. This study is designed to determine the effect of a single dose of murine CytoFeline® on FIV RNA and DNA as well as a panel of other virologic and safety markers. The Company anticipates that if the data warrants publication Dr. VandeWoude will draft and submit a manuscript detailing her results. The release of this or any data from this study is entirely dependent on Dr. VandeWoude.

On June 19, 2012, Dr. VandeWoude and Dr. Richard Trauger, the Company s Managing Director of Science, were awarded a grant of $27,000 by CSU to study the pharmacokinetics of a chimeric version of CytoFeline® in uninfected cats. The Company expects to generate and provide the chimeric version of the antibody for Dr. VandeWoude in the next six months. The Company anticipates that if the data from the study warrants publication Dr. VandeWoude and Dr. Trauger will draft and submit a manuscript detailing these results.

Manufacturing and Source for Raw Materials

We negotiated with a contract manufacturer, Vista Biologicals Corporation (Vista), to manufacture murine Cytolin® suitable for use in our current ex vivo clinical trial of Cytolin® at a cost of $565,000, all of which was paid by September 2008. In February 2010, we entered into a statement of work for the development of a humanized form of Cytolin® at a cost of $229,500. Vista entered into an assignment agreement with us to transfer all rights and title to certain inventions and applications to us in consideration for our forgiveness of certain disputed amounts under the contractual arrangements between the parties. There are ongoing negotiations related to the ultimate obligations of the Company and Vista under both the 2008 and 2010

Table of Contents

contractual arrangements. Although a murine version of Cytolin® was used for previous human experience that included approximately 200 patients treated for up to two years, as well as an encouraging uncontrolled Phase I(b)/II(a) study, and our current ex-vivo clinical trial, the Company understands that a fully-humanized version is necessary for the controlled clinical trials that are expected to follow the previous ones. On September 23, 2011, the Company filed a provisional patent application (Serial No. 61/534,942) in the United States for its humanized version of Cytolin®, a monoclonal antibody for the treatment of HIV infection. The Company is currently in discussions with potential manufacturing sites to obtain clinical grade antibody for future clinical development of Cytolin®.

Patents and Trademarks

We have a License Agreement with Allen D. Allen, our former Chief Executive Officer and former Chairman of the Company s board of directors (the Board) that gives us the exclusive right to develop, market, and profit from his technology worldwide. This includes issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057, as well as European Patent Nos. 0690725 and 1438970. In addition, Hong Kong Patent No. 1067958, Australian Patent Nos. 684074 and 2003203742, Canadian Patent No. 2156495, Austrian Patent Nos. 408418, 267019, and 1438970, Belgian Patent No. 1438970, Swiss Patent Nos. 1438970 and 0690725, German Patent Nos. 69433789 and 69435142.3, Danish Patent No. 1438970, Spanish Patent Nos. 2219647, 2314341, 04101437.4, and 94912826.8, French Patent Nos. 1438970 and 0690725, Great Britain Patent Nos. 1438970 and 069725, Greece Patent No. 3067384, Iceland Patent No. 1438970, Italian Patent Nos. 1438970 and 0690725, Luxenbourg Patent No. 1438970, Monaco Patent No. 1438970, Netherlands Patent Nos. 1438970 and 0690725, Portuguese Patent Nos. 690725 and 1438970, and Swedish Patent Nos. 0410437.4 and 94912826.8 have been obtained as well. We also acquired the federally registered trademarks, CYTODYN (U.S. Registration No. 2095498) and CYTOLIN (U.S. Registration No. 2095497), and a related design mark (U.S. Registration No. 2662777. The license acquired gives the Company the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent claims, practice methods taught by the patent claims, and exploit specified technology related to the patents. The term of the license agreement is for the life of the patents of which the first will expire in 2013. The original expiration dates on the issued U.S. Patent Nos. 5,424,066; 5,651,970 and 6,534,057 are 2013, 2014 and 2013, respectively. The original expiration dates for the foreign patents listed above are in 2013 or 2014, if the required annuity fee payments are paid by September 21, 2012. The Company s Cytolin-related patents referenced above are for a murine (mouse) version of the drug. The Company s research on Cytolin® to date has utilized the current murine version of the drug. However, on September 23, 2011, the Company filed a provisional patent application (Serial No. 61/534,942) in the United States for its humanized version of Cytolin®, a monoclonal antibody for the treatment of HIV Infection.

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Table of Contents

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Government Regulation

Regulation of Health Care Industry

The health care industry is highly regulated, and state and federal health care laws and regulations are applicable to certain aspects of our business. For example, there are federal and state health care laws and regulations that apply to the operation of clinical laboratories, the business relationships between health care providers and suppliers, the privacy and security of health information and the conduct of clinical research.

Regulation of Products

The design, testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products is regulated by numerous third parties, including the FDA, foreign governments, independent standards auditors and our customers.

In the United States, biological products have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling, import, export and safety reporting. The exercise of broad regulatory powers by the FDA through its Center for Devices and Radiological Health and its Center for Biological Evaluation and Research continues to result in increases in the amounts of testing and documentation for FDA clearance of current and new biologic products. The FDA can ban certain biological products; detain or seize adulterated or misbranded biological products; order repair, replacement or refund of these products; and require notification of health professionals and others with regard to biological products that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain certain violations of the Federal Food, Drug and Cosmetic Act, as amended, or the Public Health Service Act pertaining to certain biological products or initiate action for criminal prosecution of such violations.

The lengthy process of seeking drug approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Failure to comply with applicable regulations can result in refusal by the FDA to approve product license applications. The FDA also has the authority to revoke previously granted product approvals.

Table of Contents

Regulation of Laboratory Operations

Clinical laboratories that perform laboratory testing (except for research purposes only) on human subjects are subject to regulation under Clinical Laboratory Improvement Amendments (CLIA). CLIA regulates clinical laboratories by requiring that the laboratory be certified by the federal government, licensed by the state and comply with various operational, personnel and quality requirements intended to ensure that clinical laboratory test results are accurate, reliable and timely. State law and regulations also apply to the operation of clinical laboratories.

State Governments

Most states in which we operate have regulations that parallel federal regulations. Most states conduct periodic unannounced inspections and require licensing under such state s procedures. Our research and development activities and the manufacture and marketing of our products are and will be subject to rigorous regulations relating to product safety and efficacy by numerous governmental authorities in the United States and other countries.

Other Laws and Regulations

We are subject to various laws and regulations relating to safe working conditions, clinical, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation applying to our business that might result from any legislative or administrative action cannot be accurately predicted.

Environmental

We are subject to a variety of federal, state and local environmental protection measures. We believe that our operations comply in all material respects with applicable environmental laws and regulations. Our compliance with these regulations did not have during the past year and is not expected to have a material effect upon our capital expenditures, cash flows, earnings or competitive position.

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track. Under the Company s current business plan, much of this initial work may be sponsored and conducted by MGH, or a different clinical trial research facility, as determined by us at some point in the future and different studies may also be explored. After these trials have been initiated, the Company could enter into a strategic alliance with a larger pharmaceutical company after development has progressed to a certain point. The Company is exploring all options available to determine the most cost effective implementation of the clinical trial process.

Phase I

Phase I includes the initial introduction of an investigational new drug or biologic into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in a small number of healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase I, sufficient information about the investigational product s pharmacokinetics and pharmacological effects are obtained to permit the design of well-controlled, scientifically valid, Phase II studies.

Table of Contents

Phase II

Phase II includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase II studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people. In some cases, depending upon the need for a new drug, it may be licensed for sale in interstate commerce after a pivotal Phase II trial.

Phase III

Phase III studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase II, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit/risk relationship of the drug. Phase III studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase III studies usually include several hundred to several thousand people.

The Company may fund clinical trials using venture capital or through the sale of our common stock or other equity securities, or, at that time, may enter into a strategic alliance for completion of research and the subsequent marketing of humanized Cytolin® if approved. In the former case, and while the cost will be to some extent determined by the trial size, we currently estimate that we will need to provide additional humanized product, which we estimate will cost approximately $500,000. The Company intends to conduct one or more private placement offerings of common shares to secure the needed capital. We cannot estimate the cost of any potential follow up study or whether any of the planned private placement offerings will be successful.

Benchmark	**Some Factors That Can Cause Delays+**
Patient Outreach	Manufacturing Delays
	Documentation Delays
	IRB Delays
	Delays in Regulatory Review or Approval
	Force Majeure
Dose First Patient	Fill and Finish Delays
	Slower Than Expected Patient Enrollment
	Force Majeure
Lock Database - Begin Statistical Analysis	Slower Than Expected Patient Enrollment
	Clinical Hold
	Laboratory Error
	Protocol Deviation
	Force Majeure
Release Final Report	Additional Stratification Required
	Computer Hardware or Software Malfunction

Force Majeure

+ There are other factors, known and unknown, such as unexpected financial hardships, that can cause delays.

Table of Contents

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. We will compete with other more established biotechnology companies which have greater financial resources than we have.

Our potential competitors include entities that develop and produce therapeutic agents for treatment of human and animal disease. These include numerous public and private academic and research organizations and pharmaceutical and biotechnology companies pursuing production of, among other things, biologics from cell cultures, genetically engineered drugs and natural and chemically synthesized drugs. Almost all of these potential competitors have substantially greater capital resources, research and development capabilities, manufacturing and marketing resources and experience than we have. Our competitors may succeed in developing potential drugs or processes that are more effective or less costly than any that may be developed by us, or that gain regulatory approval prior to our potential drugs. Worldwide, there are many antiviral drugs for treating HIV and AIDS. In seeking to manufacture, distribute and market the various potential drugs we intend to develop, we face competition from established pharmaceutical companies. All of our potential competitors in this field have considerably greater financial and personnel resources than we possess. We also expect that the number of our competitors and potential competitors will increase as more potential drugs receive commercial marketing approvals from the FDA or analogous foreign regulatory agencies. Any of these competitors may be more successful than us in manufacturing, marketing and distributing our potential drugs.

Research and Development Costs

Our sponsored research and development expenses were $530,027, $480,765 and $2,759,495 in fiscal 2012, 2011 and for the period October 28, 2003 through May 31, 2012, respectively. We expect that research and development expenses will increase as we seek to expand development of our current and future product pipeline.

Employees

We have four full time employees, one part time employee, and a varying number of consultants engaged in management and product development. We are severely understaffed and will expand our employee force if we complete further financings. There can be no assurance we will be able to locate or secure suitable employees upon acceptable terms in the future.

Table of Contents

Item 1A. Risk Factors.
This item is not required for smaller reporting companies.

Item 1B. Unresolved Staff Comments.
None.

Item 2. Properties.
Our principal offices were located at 1511 Third Street, Santa Fe, New Mexico 87505 for a portion of fiscal year 2011. We leased approximately 1,200 square feet under a lease from September 1, 2010 until August 31, 2011 at $1,650 per month.

On June 7, 2011, the Board approved the relocation of the Company s principal office to Lutz, Florida. Effective as of June 15, 2011, the principal office of the Company is now located at 110 Crenshaw Lake Road, Lutz, Florida 33548. We use approximately 1,600 square feet on an at-will tenancy basis at a cost of $1,650 per month in rent plus sales tax and reimbursement for utilities. The building related to this lease is owned by an affiliate of Kenneth Van Ness, our President and Chief Executive Officer (CEO).

Item 3. Legal Proceedings.
On or about December 22, 2011, William Carmichael and Mojdeh Javadi (the Plaintiffs) filed a complaint against the Company in the Circuit Court of the State of Oregon for the County of Clackamas, alleging breach of contract. The Plaintiffs alleged that the Company entered into a contract with the Plaintiffs in November 2007, then breached the terms of the contract by failing to issue warrants to the Plaintiffs entitling them to purchase shares of the Company s stock (the Breach of Contract claims). The Plaintiffs filed an Amended Complaint against the Company on May 11, 2012 in which they asserted three additional claims each and amended the relief requested. In addition to the Breach of Contract claims, the Plaintiffs alleged in their Amended Complaint that: (i) they were third-party beneficiaries of a promise made by the Company to Nader Pourhassan in a Personal Services Agreement (the Personal Services Agreement), dated August 4, 2008 (the Third Party Beneficiary claims), (ii) they provided services to the Company and were entitled to the reasonable value for such services (the Quantum Meruit claims), and (iii) in reliance on the promises made in the Personal Services Agreement, the Company induced them to provide services to the Company and they were entitled to compensation for damages resulting from their reliance on those promises (the Promissory Estoppel claims). The Quantum Meruit and Promissory Estoppel claims were alternative claims to their Third Party Beneficiary claims. On the Breach of Contract claims, the Plaintiffs sought either compensatory damages in an amount not less than $750,000 each or the delivery of warrants to each Plaintiff to purchase 375,000 shares of the Company s common stock for $0.25 per share. With respect to the Third Party Beneficiary claims, the Plaintiffs sought a judgment requiring the Company to deliver 650,000 shares of its common stock to each Plaintiff. With respect to the Quantum Meruit claims, Plaintiffs sought compensatory damages in an amount equal to the reasonable value of their services to the Company. With respect to the Promissory Estoppel claims, the Plaintiffs sought compensation for damages resulting from their reliance on the Company s promises. The Plaintiffs also sought prejudgment interest, plus costs and disbursements incurred in the litigation. The Company filed an answer to the complaint on February 15, 2012. An answer to the Amended Complaint was filed on May 21, 2012.

Table of Contents

On July 27, 2012, the Company entered into a Settlement Agreement and Mutual Release (the Settlement Agreement) with the above Plaintiffs. Pursuant to the Settlement Agreement, the Company issued 200,000 shares of the Company s common stock (Shares) to each of the Plaintiffs, for an aggregate total of 400,000 Shares. In addition, the Company issued warrants (Warrants) to purchase up to 375,000 Shares to each of the Plaintiffs, for an aggregate total of 750,000 Warrants. The Warrants are immediately exercisable at $0.25 per Share and shall expire on August 15, 2012. The Company issued the Shares and the Warrants to the Plaintiffs in exchange for their full and complete release of any and all claims against the Company as of July 27, 2012. Pursuant to and in accordance with the Settlement Agreement, on July 30, 2012, the Plaintiffs also dismissed with prejudice and without any award of costs, disbursements or attorney s fees, their Amended Complaint against the Company filed in the Circuit Court of the State of Oregon for the County of Clackamas. As of May 31, 2012, the Company recognized approximately $540,000 and $388,000 of compensation expense related to the Warrant grant, and the issuance of the Shares, respectively.

In addition, from time to time, we are involved in claims and suits that arise in the ordinary course of our business. Management currently believes that resolving any such claims against us will not have a material adverse impact on our business, financial position or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Over-the-Counter Bulletin Board under the ticker symbol CYDY.

The table below provides the high and low sales prices of our common stock for the periods indicated, as reported by the Over-the-Counter Bulletin Board quotations system:

Price Range of Outstanding Common Stock

Year Ended May 31, 2012	High	Low
First Quarter Ended August 31, 2011	$ 2.75	$ 1.70
Second Quarter Ended November 30, 2011	$ 3.00	$ 1.85
Third Quarter Ended February 29, 2012	$ 4.40	$ 2.52
Fourth Quarter Ended May 31, 2012	$ 2.80	$ 1.46

Table of Contents

Year Ended May 31, 2011	High	Low
First Quarter Ended August 31, 2010	$ 1.54	$ 0.75
Second Quarter Ended November 30, 2010	$ 1.40	$ 0.95
Third Quarter Ended February 28, 2011	$ 2.29	$ 1.15
Fourth Quarter Ended May 31, 2011	$ 4.40	$ 1.70

Holders

The number of record holders of our common stock on May 31, 2012 was approximately 1,256. This number includes shareholders that hold the shares in street name with brokers, dealers and other financial institutions. There have been 802,269 shares issued by the Company after May 31, 2012.

Dividends

Holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board. We have not paid any cash dividends since inception on our common stock and do not anticipate paying any in the foreseeable future. Management s current policy is to retain earnings, if any, for use in our operations.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding outstanding options and rights and shares reserved for future issuance under our existing equity compensation plans as of May 31, 2012.

Equity Compensation Plan Information

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,658,500	$ 1.48	3,941,500
Equity compensation plans not approved by security holders (1)	6,669,164	$ 1.66	0
Total	10,327,664	$ 1.60	3,941,500

(1) Represents warrants issued by the Company (i) in connection with previous issuances of debt and previous private placements of the Company s securities, (ii) as consideration for certain consulting services provided to the Company, and (iii) as consideration for the release of certain claims against the Company, and also includes the issuance of options (i) prior to the adoption of the 2004 Incentive Plan, (ii) to certain of our employees under their existing employment agreements, and (iii) to compensate Board members for their service as directors.

Table of Contents

Recent Sales of Unregistered Securities

On May 21, 2012, in connection with and as consideration for their services as members of the Board, the Company issued 3,743 shares of the Company s common stock to each of Jordan Naydenov, Ronald Tropp, George Dembow and Gregory Gould. The Company also issued 1,703 shares of the Company s common stock to Anthony Caracciolo, prorated for the period of his service as a Board member. The shares of common stock will vest in equal daily installments and will be fully vested on May 31, 2012.

During the three months ended May 31, 2012, we issued to an investor upon exercise of warrants, 10,000 shares of common stock of the Company at an exercise price of $1.00 per share, for proceeds of $10,000.

During the three months ended May 31, 2012, 45,900 shares of Series B were converted into 459,000 shares of common stock. The Series B is convertible into 10 shares of the Company s common stock including any accrued dividend, with an effective fixed conversion price of $0.50 per share. During the three months ended May 31, 2012, we issued 42,900 shares of common stock related to these dividends.

We issued and sold the aforementioned warrants, options, and common stock without registration pursuant to Section 4(2) of the Securities Act of 1933, as amended (the Securities Act), Rule 506, Rule 701 and, as applicable, Regulation S promulgated thereunder.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of any of our equity securities during the three months ended May 31, 2012.

Item 6. Selected Financial Data.

This item is not required for smaller reporting companies.

Table of Contents

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Annual Report, including our consolidated financial statements and related notes appearing elsewhere herein. This discussion and analysis contains forward-looking statements including information about possible or assumed results of our financial conditions, operations, plans, objectives and performance that involve risk, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements.

Results of Operations

Results of operations for the year ended May 31, 2012 compared to May 31, 2011 are as follows:

For the years ended May 31, 2012 and 2011, we had no activities that produced revenues from operations.

For the year ended May 31, 2012, we had a net loss of approximately $7,474,000 compared to a net loss of approximately $3,720,000 for the corresponding period in 2011. For the year ended May 31, 2012 and 2011, we incurred operating expenses consisting primarily of stock-based compensation, accounting and consulting, research and development, salary, legal expenses, and various other selling and administrative expenses.

The operating expenses for the years ended May 31, 2012 and 2011 are as follows:

	2012	2011
Accounting and consulting	$ 524,000	$ 274,000
Stock-based compensation	2,858,000	1,186,000
Legal	1,469,000	689,000
Salaries	1,623,000	700,000
Research and development	530,000	481,000
Depreciation and amortization	2,000	3,000
Other	450,000	365,000
Total	**$ 7,456,000**	**$ 3,698,000**

Accounting and consulting expenses increased approximately $250,000 from $274,000 in fiscal year 2011 to approximately $524,000 at May 31, 2012. Accounting expenses increased as the Company utilized more temporary accounting staff, as well as increased edgarization costs related to the Company s increased filings with the Securities and Exchange Commission (SEC). The increase in consulting expenses relates primarily to the issuance of common stock to consultants for services, as well as the Company entering into a consulting agreement with the Company s former CEO in the first quarter of fiscal year 2012.

Stock-based compensation increased approximately $1,672,000 from approximately $1,186,000 at May 31, 2011 to $2,858,000 at May 31, 2012. The increase relates to options grants made to certain executives of the Company pursuant to employment agreements, as well

Table of Contents

as warrants granted to certain consultants with immediate vesting rights. Additionally, as disclosed in Item 3. Legal Proceedings and footnotes 9 and 11 to the consolidated financial statements, the Company granted warrants and common stock pursuant to the Settlement Agreement. During fiscal year 2011, there were less option grants, and no grants with immediate vesting rights. The Company expects to continue to grant stock options in the future, and accordingly, stock-based compensation should continue to be a significant expense in the future.

Legal expenses increased approximately $780,000 from approximately $689,000 at May 31, 2011 to $1,469,000 at May 31, 2012 due to a variety of matters, including assistance with: (i) litigation as discussed at footnote 9 of the consolidated financial statements; (ii) preparation or review and negotiation of contracts such as with third-party providers and employment agreements; (iii) responding to an investigation by the SEC; (iv) the Company s SEC filings and corporate compliance; (v) ongoing claims and litigation and other disputes and the negotiation of associated proposed and/or final settlements with certain third parties; (vi) the Company s ongoing fundraising efforts and related securities law research with respect to the Company s past and current fundraising efforts; (vii) extensive negotiation and drafting of the Asset Purchase Agreement and related documentation relating to the Company s proposed acquisition of PRO 140 from Progenics Pharmaceuticals, Inc., as discussed in footnote 11 to the consolidated financial statements; and (viii) extensive research and review of Company records in order to facilitate bringing the Company s SEC filings into compliance. The trend in the Company s legal expenses will depend on the Company s ability to raise proceeds and to hire additional staff who can perform certain functions that can help defray legal expenses.

Salaries increased approximately $923,000 from approximately $700,000 in fiscal year 2011 to $1,623,000 in fiscal year 2012. The significant increase relates to the execution of executive employment contracts during fiscal year 2012, as well as the payment of certain discretionary bonuses to executives. The executive salaries in fiscal 2012 were significantly higher for certain executives relative to fiscal year 2011. Bonuses to executives are either based on achievement of targeted annual performance goals recommended by the compensation committee and approved by the Board, or are discretionary in nature based on Board approval. During fiscal year 2012, the Company granted discretionary bonuses of approximately $335,000. There were no bonuses granted during fiscal year 2011.

Research and development expenses increased approximately $49,000 from approximately $481,000 in fiscal year 2011 to $530,000 in fiscal year 2012. The increase relates primarily to the Company entering into a consulting agreement for research related to the development of FIV therapeutics.

Other expenses are comprised of various selling and administrative expenses which increased approximately $85,000 from approximately $365,000 in fiscal year 2011 to $450,000 in fiscal year 2012. The increase relates primarily to increases in investor relation costs, healthcare costs pursuant to employment agreements, and numerous other smaller increases.

The increase or decrease in the above expenses will depend on the Company s ability to raise additional capital and ultimately fund the Company s clinical trials, and fund other operating costs as deemed necessary.

Table of Contents

Rescission Liability

The Company estimates an amount that is a probable indicator of the rescission liability and has recorded rescission liabilities for May 31, 2012 and May 31, 2011 of approximately $3,749,000 and $4,851,000, respectively. These amounts represent the believed potential rescission liability as of the dates presented, including any contingent interest payable to investors who accept the rescission right, and forfeit their shares. For the purpose of calculating and disclosing rescission liability, the Company has assumed that portions of the state claims are barred by the statutes of limitations of certain states based upon a literal interpretation of the applicable statute. Although the Company has assumed that affirmative defenses based upon the expiration of the statutes of limitations in these states may be generally available to bar these state claims, it has not had legal counsel undertake a detailed analysis of case law that might apply to defer or avoid application of a bar to such claims; thus, if rescission claims are made for those assumed to be barred by a statute of limitations and such claims are contested by the Company, until such affirmative defenses are ruled upon by judge in a proceeding adjudicating the rights at issue, no assurances can be made that, if asserted, such defenses would actually bar the rescission claims in these states. See Footnote 3 of our Consolidated Financial Statements on page 51 for further information regarding these rescission liabilities.

Accrued Incentive Stock Compensation

On August 4, 2008, the Company entered into the Personal Services Agreement with Nader Pourhassan. The Personal Services Agreement provided for compensation to Dr. Pourhassan at an annual salary of $200,000. Additionally, as incentive compensation, Dr. Pourhassan s personal assistant and one additional person were to receive 50,000 common shares each of Company stock for every $500,000 in capital received by the Company through Dr. Pourhassan s efforts. As of May 31, 2010, the Company accrued $1,180,000 related to the Personal Services Agreement. Subsequent to the fiscal year ended May 31, 2011, Dr. Pourhassan and the Company entered into a Mutual Release and Personal Services Termination Agreement (the MRPSTA) which relieves the Company of liability for any claims of compensation under the Personal Services Agreement. Simultaneously, with the signing of the MRPSTA, Dr. Pourhassan and the Company entered into a new Employment and Non-Compete Agreement whereby Dr. Pourhassan will serve as Managing Director of Business Development at an annual salary of $200,000. See Footnote 3 of our Consolidated Financial Statements on page 51 for further information.

The Company had been accruing stock compensation and deferred offering costs related to the Personal Services Agreement as described at Note 3. Upon the signing of the MRPSTA, the Company at May 31, 2011 reversed all accrued stock compensation and deferring offering costs, as the Company currently has no further obligations under the Personal Services Agreement.

Liquidity and Capital Resources.

On May 31, 2012, we had negative working capital of approximately $4,007,000 as compared to a negative working capital of approximately $5,022,000 on May 31, 2011.

Table of Contents

Cash Flows

Net cash used in operating activities was approximately $4,391,000 during fiscal year 2012, which reflects an increase of approximately $2,570,000 from net cash used in operating activities of approximately $1,821,000 in 2011. The increase in the net cash used in operating activities for the above periods was primarily attributable to the following:

Net loss increased approximately $3,755,000; and

Accounts payable, accrued salary, accrued interest, and accrued liabilities decreased approximately $679,000.

The above increases were partially offset by stock-based compensation increasing approximately $1,672,000 from 2011 to 2012.

There were no other significant changes in cash used in operating activities from 2011 to 2012.

There were no material changes in cash flows from investing activities from 2011 to 2012.

Cash flows provided by financing activities of approximately $3,638,000 during fiscal year 2012 increased approximately $2,510,000 from approximately $1,128,000 during 2011. The increase in cash provided by financing activities for the above periods was attributable primarily to the increase in proceeds from the sale of common stock and the exercise of common stock options and warrants.

There were no other significant changes in cash provided by financing activities from 2011 to 2012.

As shown in the accompanying consolidated financial statements, for the year ended May 31, 2012 and 2011, and since October 28, 2003 through May 31, 2012 we incurred net losses of approximately $7,474,000 and $3,720,000 and $22,833,000, respectively. As of May 31, 2012, we have not emerged from the development stage. In view of these matters, our ability to continue as a going concern is dependent upon our ability to begin operations and to achieve a level of profitability. Since inception, we have financed our activities principally from the sale of public and private equity securities and proceeds from notes payable. We intend to finance our future development activities and our working capital needs largely from the sale of equity securities with some additional funding from other traditional financing sources.

As previously mentioned, since October 28, 2003, we have financed our operations largely from the sale of common stock and preferred stock and proceeds from notes payable. From October 28, 2003 through May 31, 2012 we raised cash of approximately $10,504,000 (net of offering costs) through private placements of common stock, treasury stock and preferred stock financings and $1,537,000 through the issuance related party notes payable and convertible notes. The Company has raised approximately $612,000 from the issuance of common stock and preferred stock in conjunction with certain acquisitions in prior years. Additionally, the Company raised approximately $355,000 from the exercise of common stock options and warrants. In April 2010, our shareholders voted to amend our Articles of Incorporation to increase the number of authorized shares of common stock to 100,000,000 shares; accordingly, we intend to continue to finance our operations through the sale of our shares.

Table of Contents

Since October 28, 2003 through May 31, 2012, we have incurred approximately $2,759,000 of research and development costs and approximately $22,295,000 in operating expenses. We have incurred significant net losses and negative cash flows from operations since our inception. As of May 31, 2012, we had an accumulated deficit of approximately $24,435,000 and negative working capital of approximately $4,007,000.

We anticipate that cash used in product development and operations, especially in the marketing, production and sale of our products will increase significantly in the future. We currently do not have any significant material commitments related to capital expenditures. As described above, we do have material commitments related to our current Study (as defined above) of our product with MGH, and have potential obligations under our contracts with Vista.

Going Concern

We will require additional funding in order to continue with research and development efforts.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements, the Company is currently in the development stage with losses for all periods presented. As of May 31, 2012 these factors, among others, raise substantial doubt about the Company s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company s continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its medical treatments, obtain FDA approval, outsource manufacturing of the treatments, and ultimately to attain profitability. The Company intends to seek additional funding through equity offerings or licensing agreements to fund its business plan. There is no assurance that the Company will be successful in these endeavors.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Table of Contents

We believe that the following critical policies affect our more significant judgments and estimates used in preparation of our consolidated financial statements.

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant utilizing certain assumptions that require judgments and estimates. These assumptions include estimates for volatility, expected term, and risk-free interest rates in determining the fair value of the stock-based awards.

We issue common stock to consultants for various services. Costs for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more readily measurable. This determination requires judgment in terms of the consideration being measured.

We estimated an amount that is a probable indicator of our rescission liability and will record rescission liabilities for May 31, 2012 and May 31, 2011 of $3,749,000 and $4,851,000, respectively. These amounts represent the believed potential rescission liability as of the dates presented, including any contingent interest payable to investors who accept the rescission right, and forfeit their shares. For the purpose of calculating and disclosing rescission liability, the Company has assumed that portions of the state claims are barred by the statutes of limitations of certain states based upon a literal interpretation of the applicable statute. Although the Company has assumed that affirmative defenses based upon the expiration of the statutes of limitations in these states may be generally available to bar these state claims, it has not had legal counsel undertake a detailed analysis of case law that might apply to defer or avoid application of a bar to such claims; thus, if rescission claims are made for those assumed to be barred by a statute of limitations and such claims are contested by the Company, until such affirmative defenses are ruled upon by judge in a proceeding adjudicating the rights at issue, no assurances can be made that, if asserted, such defenses would actually bar the rescission claims in these states. See Footnote 3 of our Consolidated Financial Statements on page 51 for further information.

Table of Contents

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

This item is not required for smaller reporting companies.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

CYTODYN INC.

(A DEVELOPMENT STAGE COMPANY)

CONTENTS PAGE #

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders

CytoDyn Inc. (A Development Stage Company)

Lutz, Florida

We have audited the accompanying consolidated balance sheets of CytoDyn Inc. (a development stage company) as of May 31, 2012 and 2011 and the related consolidated statements of operations, changes in stockholders equity (deficit), and cash flows for the years then ended and the period from October 28, 2003 through May 31, 2012. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required at this time, to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CytoDyn Inc. as of May 31, 2012 and 2011 and the results of its operations and its cash flows for the years then ended and the period from October 28, 2003 through May 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company incurred a net loss of $7,474,224 for the year ended May 31, 2012, has a working capital deficit of $4,006,969, and has an accumulated deficit of $24,434,518 from the date of inception through May 31, 2012, which raises a substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Pender Newkirk & Company LLP
Pender Newkirk & Company LLP

Certified Public Accountants

Tampa, Florida

August 21, 2012

Table of Contents

CytoDyn Inc.

(A Development Stage Company)

Consolidated Balance Sheets

	May 31, 2012	2011
Assets		
Current Assets:		
Cash	$ 284,991	$ 1,037,818
Prepaid expenses	65,982	59,275
Deferred Offering Costs	677,327	876,423
Total current assets	1,028,300	1,973,516
Furniture and equipment, net	800	5,374
Other Assets	41,735	15,748
	$ 1,070,835	$ 1,994,638
Liabilities and Shareholders (deficit)		
Current liabilities:		
Accounts payable	$ 831,336	$ 932,996
Accrued liabilities	150,573	756
Accrued salaries	189,249	
Indebtedness to related parties - short-term portion	74,493	148,985
Accrued interest payable	40,618	26,696
Deposits on stock purchases		1,035,000
Stock rescission liability	3,749,000	4,851,000
Total current liabilities	5,035,269	6,995,433
Long-Term Liabilities		
Convertible notes payable, net	9,000	6,937
Total Liabilities	5,044,269	7,002,370
Shareholders (deficit):		
Series B Convertible stock preferred stock, no par value; 400,000 shares authorized, 98,900 and 311,800 shares issued and outstanding at May 31, 2012 and 2011, respectively	451,993	1,566,016
Common stock, no par value; 100,000,000 shares authorized, 28,636,530 and 22,290,982 outstanding at May 31, 2012 and 2011, respectively; 28,836,530 and 22,490,982 issued at May 31, 2012 and May 31, 2011, respectively	15,150,261	9,147,325
Common stock payable	388,000	
Additional paid-in capital	8,020,533	5,877,141
Common and Preferred stock subject to rescission	(3,749,000)	(4,851,000)
Treasury stock, at cost, 200,000 and 200,000 shares held at May 31, 2012 and 2011, respectively	(100,000)	(100,000)
Additional paid-in capital - treasury stock	299,297	313,080
Accumulated deficit on unrelated dormant operations	(1,601,912)	(1,601,912)
Deficit accumulated during development stage	(22,832,606)	(15,358,382)
Total shareholders (deficit)	(3,973,434)	(5,007,732)

	$ 1,070,835	$ 1,994,638

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Operations

	Year ended May 31,		October 28, 2003 through
	2012	2011	May 31, 2012
Operating expenses:			
General and administrative	$ 5,454,477	$ 2,525,661	$ 16,461,892
Amortization / depreciation	2,013	2,880	182,862
Research and development	530,027	480,765	2,759,495
Legal fees	1,469,129	688,933	2,890,631
Total operating expenses	7,455,646	3,698,239	22,294,880
Operating loss	(7,455,646)	(3,698,239)	(22,294,880)
Interest income			1,627
Extinguishment of debt			337,342
Interest expense:			
Interest on convertible debt	(2,063)		(736,926)
Interest on notes payable	(16,515)	(21,449)	(139,769)
Loss before income taxes	(7,474,224)	(3,719,688)	(22,832,606)
Income tax provision			
Net loss	$ (7,474,224)	$ (3,719,688)	$ (22,832,606)
Constructive preferred stock dividends	$	$	$ (6,000,000)
Convertible preferred stock dividends	$ (88,743)	$ (8,550)	$ (97,293)
Net loss applicable to common shareholders	$ (7,562,967)	$ (3,728,238)	$ (28,929,899)
Basic and diluted loss per share	$ (0.31)	$ (0.18)	$ (2.04)
Basic and diluted weighted average common shares outstanding	24,618,812	21,076,430	14,204,081

See accompanying notes to consolidated financial statements.

Table of Contents

CytoDyn Inc.

(A Development Stage Company)

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Period October 28, 2003 through May 31, 2012

	Preferred Stock		Common Stock		Additional	Subject to
	Shares	Amount	Shares	Amount	Paid-In Capital	Recession
Balance at October 28, 2003, following recapitalization			6,252,640	$ 1,425,334	23,502	
February through April 2004, sale of common stock less offering costs of $54,000 ($.30/share)			1,800,000	486,000		